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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/717,002 | 11/19/2003 | Yucel Donmez | | 7609 |

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YUCEL DONMEZ
3RD FLOOR
5520 N. ARTESIAN AVE
CHICAGO, IL 60625

| EXAMINER | |
|---|---|
| LEITH, PATRICIA A | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1654 | |

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/717,002 | DONMEZ, YUCEL | |
| | Examiner | Art Unit | |
| | Patricia Leith | 1654 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-3 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-3 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Claims 1-3 are pending in the application.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to

make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

Inventions targeted for human therapy bear a heavy responsibility to provide supporting evidence because of the unpredictability in biological responses to therapeutic treatments. The standard of enablement is higher for such inventions because effective treatments for disease conditions are relatively rare, and may be unbelievable in the absence of strong supporting evidence. Claims drawn to pharmaceutically acceptable compositions and to methods of administering compounds to humans generally require supporting evidence because of the unpredictability in biological responses to therapeutic treatments.

The Instant specification is lacking guidance which would necessarily allow the ordinary artisan to make the enabled composition of the present invention. The instant disclosure does not contain information regarding the plant extraction procedures.

Thus, the skilled artesian is left to his/her own judgment to choose which extract the Instant specification is referring to. In order to make such a judgment, unnecessary experimentation would have to be performed in order to assess the effectiveness of each respective extract.

The art of phytomedicine is highly unpredictable. Different types of extracts from the same plant would be expected to display different results in an individual due to the diversified phytochemical constituents in each respective extract. Taking the ginkgo extracts for example, it is known that ginkgo biloba plants produce effectively distinct products when subject to various extraction techniques. These different products may necessarily produce a myriad of different effects in an individual. For example, De Long et al. (US 6,030,621) taught that;

> "Great efforts have been made in the 1990's to enrich the active therapeutic components of Ginkgo biloba extract and to reduce its content of ginkgolic acids. At the same time, possibilities have been exploited to provide specific combinations of the effective components of Ginkgo biloba extract for different therapies. A combination of the ginkgolide components and the flavone glycosides will shift the active profile of the extract towards the anti-PAF-effects. By contrast, a combination of the bilobalide and the flavone glycosides will apply the active profile more effectively against encephalopathies, cerebral edemas, demyelinating neuropathies and myelopathies....." (Col.2, lines 10-21)

Since any given biological source contains thousands of extractable compounds, each with its own particular extraction properties, the nature of the resulting "extract" will

depend on the conditions of the extraction and the solvent used. For example, is the extract obtained via extraction with water, a polar solvent, a non-polar solvent, or an acid or base, at what temperature, or is it a squeezed extract? It is well accepted in the natural products and herbal art, that extraction of a biological source with one of various distinct solvents has a profound impact on the final product with respect to the presence, amounts, and/or ratios of active ingredients obtained, and, thus, on the ability of the "extract" to provide the desired functional effect(s) claimed and/or disclosed. Since each individual extraction procedure would necessarily bring about a different product, it is unpredictable how the difference would affect an individual *in-vivo*. There is no guidance or direction presented to direct one to determine which isoflavones would work in the broadly claimed invention which is a complex and unpredictable art.

Clearly, plants such as gingko biloba as well as green tea contain a myriad of phytochemicals that have distinct pharmacological capabilities. Thus, since the Instant specification as filed is not entirely clear as to exactly what green tea extract is used to prepare a composition for treating hair loss, it would require undue experimentation in order to create a composition which would display parallel results which Applicant[s] have provided in the disclosure regarding hair loss.

Therefore because of the large number of inoperable embodiments claimed, it would require a substantial inventive contribution of the ordinary artisan to practice the

claimed invention. It may be true the Applicant is able to make the invention, however the application is directed toward one of ordinary skill in the art. It is not seen the claims are set forth in clear, concise and exact terms to enable someone other than the Applicant to make the invention **which is a requirement of the statute**. It has been well established that disclosure in an application shall inform those skilled in the art how to use applicant's alleged discovery, not how to find out how to use it for themselves." In re Gardner et al., 166 USPQ 138 (CCPA 1970).

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Leith
Primary Examiner
Art Unit 1654

09/29/04